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# PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): WM-5463 (112713-898)

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

| Application Number | Filed |
|---|---|
| 09/831,121 | August 16, 2001 |

First Named Inventor: Yves Delmotte et al.

| Art Unit | Examiner |
|---|---|
| 1771 | Hai Vo |

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant/inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [X] attorney or agent of record. Registration number Ted J. Barthel (Reg. No. 48,769).
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Signature

Ted J. Barthel
Typed or printed name

312 578-6846
Telephone number

April 19, 2006
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

- [ ] *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | |
|---|---|
| Applicant(s): | Yves Delmotte et al. |
| Appl. No.: | 09/831,121 |
| Conf. No.: | 8727 |
| Filed: | August 16, 2001 |
| Title: | ELEMENT PROVIDED WITH A FIBRIN LAYER, PREPARATION AND USE THEREOF |
| Art Unit: | 1771 |
| Examiner: | Hai Vo |
| Docket No.: | WM-5463 (112713-898) |

Mail Stop Amendment
Commissioner for Patents
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Alexandria, VA 22313-1450

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Sir:

In response to the final Office Action dated January 20, 2006 please find the following:

Form PTO/SB/33, Pre-Appeal Brief Request for Review; and

Form PTO/SB/31, Notice of Appeal.

**Remarks** begin on page 2 of this paper.

## REMARKS

This Paper is submitted in response to the final Office Action mailed on January 20, 2006 and having a shortened statutory response period ending on April 20, 2006. This Paper is submitted within the shortened statutory response period. The Commissioner is hereby authorized to charge the amount of $500.00 for the Notice of Appeal and any additional fees to Deposit Account No. 02-1818.

Claims 46-49, 51-55, 57-71, 73-74, 76-89, and 131-134 are currently pending. Claims 50, 56, 72, and 75 have been canceled. Claims 90-130 have been withdrawn.

Claims 46-49, 51-55, 57-71, 73-74, 76-89, and 131-134 were rejected under 35 U.S.C. §112 2nd paragraph as the term "in the range of about 10 microns to greater than about 20 microns" was alleged to be unclear. Applicants intend to address the §112 rejection after the Panel Decision from Pre-Appeal Brief Review.

Claims 46-55, 59-71, 73-74, 76-83, 89, and 131-134 were rejected under 35 U.S.C. § 103(a) for allegedly being obvious over U.S. Patent No. 5,272,074 to Rubens (*Rubens)* in view of U.S. Patent No. 5,744,515 to Clapper (*Clapper*) as evidenced by European Patent No. 366,564 to Sawamoto et al. (*Sawamoto*). Claims 73, 74, 76, and 77 were rejected under 35 U.S.C. §103(a) for allegedly being obvious over *Rubens* in view of *Clapper* as evidenced by *Sawamoto* in further view of U.S. Patent No. 5,824,080 to Lamuraglia (*Lamuraglia*) as evidenced by U.S. Patent No. 5,242,792 to Rudolph et al. (*Rudolph*). Claims 84-88 were rejected under 35 U.S.C. §103(a) for allegedly being obvious over *Rubens* in view of *Clapper* as evidenced by *Sawamoto* in view of International Publication No. WO 96/22115 to Delmotte (*Delmotte*) or *Rubens* in view of U.S. Patent No. 5,882,354 to Brauker et al. (*Brauker*), and *Clapper* as evidenced by *Sawamoto* in view of *Delmotte.* Claims 46-49, 51-55, 57-71, 78-83, 89 and 131-134 were rejected under 35 U.S.C. §103(a) for allegedly being obvious over *Rubens* in view of *Brauker*, and *Clapper* as evidenced by *Sawamoto.* Claims 73, 74, 76, and 77 were rejected under 35 U.S.C. §103(a) for allegedly being obvious over *Rubens* in view of *Brauker* and *Clapper* as evidenced by *Sawamoto* in further view of *Lamuraglia* as evidenced by *Rudolph.* Claims 46, 48, 49, 52, 53, 56-71, 73, 74, 76-89 and 131-134 were rejected under 35 U.S.C. § 103(a) for allegedly being obvious over *Delmotte.* Applicants respectfully disagree with and traverse these rejections for the reasons set forth below.

*Sawamoto* (EP 366, 564) **teaches away** from a non-hydrolyzed fibrin network as recited in the present claims. *Sawamoto's* disclosure of a substrate coated with a hydrolyzed fibrin layer teaches away from the claimed non-hydrolyzed fibrin. *Sawamoto*, page 4 lines 35-37, page 5 lines 1-3, page 7 lines 14-15, page 7 lines 26-27, page 7 lines 42-44. In fact, the Examiner has **admitted** that *Sawamoto* teaches away from the claimed subject matter. *See* Office Action dated January 20, 2006 at ¶1. Teaching away is a *per se* demonstration of non-obviousness. *In re Dow Chemical Co.*, 837 F.2d 469 (Fed. Cir. 1988). Accordingly, a reference, such as *Sawamoto*, that teaches away cannot serve to create a *prima facie* case of obviousness. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). As *Sawamoto* clearly teaches away from the present claims, as admitted by the Examiner, Applicants respectfully submit that the rejections based on *Sawamoto* are improper and be withdrawn.

It is an axiom of patent law that the references must provide some reasonable expectation that a result could be successful. *In re Clinton*, 527 F.2d 1226, 1228 (CCPA 1976). The present application discusses the problems associated with extending fibrin-forming components into small pores of support substrates and subsequently removing fibrinogen therefrom. Accordingly, the present application solves these problems by providing a novel and inventive method that applies a suction force to the porous support in order 1) to draw fibrin-forming components into the small pores and 2) subsequently remove unreacted fibrinogen from the small pores. The resulting element of this method is recited in the present claims. As none of the cited references address the problem of delivering fibrin (not to mention fibrinogen-free fibrin) into small pores of support material, no reference provides any expectation of success of providing fibrin—let alone fibrinogen-free fibrin—into small pores of a support. Accordingly, any allegation that the extent to which the fibrin is present in the pores is a "result-effective variable" is without merit as the cited references 1) fail to address the problem of fibrin delivery into small pores and 2) correspondingly lack any expectation of success to deliver fibrin into pores having a diameter of only 10μm-20μm.

In this regard, the cited references, *Rubens*, *Clapper, Delmotte, Brauker, Lamuraglia,* and/or *Rudolph,* either alone or in combination, fail to disclose or suggest a reasonable expectation of forming an element with a support having 1) pores with a diameter of only 10μm-20μm and 2) a fibrinogen-free fibrin layer that extends into each pore 3) a distance of about 2-20μm as recited in the present claims. *Rubens* has no disclosure whatsoever regarding a

substrate with fibrin extending into the pores thereof. In fact, the Examiner has admitted the same. *See* Office Action dated January 20, 2006, ¶ 7 at pp 4-5.

*Clapper* merely discloses a porous ePTFE material that may bear an immobilized adhesion molecule. *Clapper*, col. 5 lines 35-40. Consequently, *Clapper*, is wholly silent regarding a support having fibrinogen-free fibrin extending 2-20μm into the pores of the ePTFE material.

Wholly lacking in *Brauker* is any disclosure regarding fibrin, let alone fibrinogen-free fibrin. *Brauker* merely discloses an implant material. With no mention of fibrin, *Brauker* cannot disclose or suggest an element with a support having pores with a diameter of only 1) 10μm-20μm and 2) a fibrinogen-free fibrin layer that extends into each pore 3) a distance of about 2-20μm as recited in the present claims.

Regarding *Delmotte,* the Examiner has admitted that *Delmotte* fails to disclose a support 1) having pores with a diameter of only 10μm-20μm, 2) the support having a fibrinogen-free fibrin layer that extends into each pore 3) a distance of about 2-20μm as recited in the present claims. In fact, *Delmotte* has no disclosure directed to the problems associated with the provision of fibrinogen-free fibrin in the small pores of a support substrate or a solution to this problem. Accordingly, the assertion that the extent to which the fibrin is present in the pores is a "result-effective variable" is without merit as *Delmotte* 1) has no disclosure directed to the problem of fibrin delivery into small pores and 2) provides no solution to this problem. With no disclosure directed to problem and/or solution of providing fibrinogen-free fibrin into small pores of a substrate, *Delmotte* correspondingly lacks any expectation of success to deliver fibrin into pores having a diameter of only 10μm-20μm.

*Lamuraglia* and *Rudolph* have no disclosure directed to 1) a substrate having pores with varying sizes and 2) fibrinogen-free fibrin extending 2-20μm into each pore as recited in the claims. *Lamuraglia* has no disclosure whatsoever directed to a fibrin-coated substrate, let alone a fibrinogen-free fibrin as recited in the claims. Rather, *Lamuraglia* discloses a method of using photodynamic therapy to prepare arterial allografts for *in vivo* applications. *Lamuraglia*, col. 4 line 66 through col. 5 line 5. *Rudolph* similarly has no disclosure whatsoever directed to fibrin, let alone a fibrinogen-free fibrin coating on a porous substrate. Rather, *Rudolph* discloses a preservation agent to improve the long term storage of red blood cells. *Rudolph*, col. 3 lines 28-40. As neither *Lamuraglia* nor *Rudolph* has any disclosure directed to 1) a substrate having

pores with varying sizes or 2) fibrin, *Lamuraglia* and *Rudolph* fail to disclose of suggest the recited subject matter.

## CONCLUSION

For the foregoing reasons, Applicants respectfully submit that the above-identified patent application is now in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY _____

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Dated: April 19, 2006